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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,280	01/20/2004	Joanne Peart	02940086CA	6861
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WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.			EXAMINER	
11491 SUNSET HILLS ROAD			ALSTRUM ACEVEDO, JAMES HENRY	
SUITE 340			ART UNIT	PAPER NUMBER
RESTON, VA 20190			1616	
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			06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/759,280	PEART ET AL.
	Examiner	Art Unit
	James H. Alstrum-Acevedo	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 April 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 43, 46-48, 50, 52-55, and 57-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 43, 46-48, 50, 52-55, and 57-60 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claims 43, 46-48, 50, 52-55, and 57-60 are pending. Applicants had previously cancelled claims 1-42, 44-45, 49, 51, and 56. Claims 57-60 are new. Receipt and consideration of Applicant's amended claim set and arguments/remarks submitted on April 19, 2007 are acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 19, 2007 has been entered.

Moot Rejections/objections

All rejections and/or objections of claims 23, 25-42, 44, and 45 cited in the previous office action mailed on January 9, 2007 are moot, because said claims have been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 43, 46-48, 50, and 53-55 under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804,592) in view of McNally et al. (U.S. Patent No. 5,653,961) is maintained for the reasons of record set forth in the office action mailed on December 28, 2005. New claims 57-60 are appended to this rejection for the reasons of record. In summary, **claims 43, 46-48, 50, 53-55, and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804,592) in view of McNally et al. (U.S. Patent No. 5,653,961).**

The rejection of claim 52 under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804592) in view of McNally et al. (U.S. Patent No. 5,653,961) as applied to 43, 46-48, 50, 51, and 53-55 above, and further in view of Pars et al. (U.S. Patent No. 3,728,360) **is maintained** for the reasons of record set forth in the office action mailed on December 28, 2005.

Response to Arguments

Applicant's arguments filed April 19, 2007 have been fully considered but they are not persuasive. Applicants have traversed the above outstanding rejections made under 35 U.S.C. §103(a) by (1) attacking the primary references individually without addressing the merits of the teachings of the combined prior art; (2) asserting that Applicants have presumably rebutted any allegation of the operability of Mechoulam or Volicer based in part on the Weers declaration submitted on April 4, 2006; and (3) implicitly arguing that the rejections are improper under 35 U.S.C. §103(a) because the primary references do not anticipate the rejected claims.

The Examiner respectfully disagrees with Applicants' traversal arguments. In response to applicant's arguments (1)/(3) against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants have failed to consider the teachings of the combined prior art references, and especially the explicit/implicit teachings and suggestions of the various cited prior art references. The explanation of the deficiencies of the Weers declaration have been explicitly set forth on the record on pages 5-12

of the office action mailed on January 9, 2007 and is incorporated herein by reference in its totality. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

The rejection of claims 43, 48, 50, and 52-55 under 35 U.S.C. 103(a) as being unpatentable over Pars et al. (U.S. Patent No. 3,728,360) in view of McNally et al. (U.S. Patent No. 5,653,961) is maintained for the reasons of record set forth in the office action mailed on December 28, 2005. New claims 57-60 are appended to this rejection for the reasons of record. In summary, claims 43, 48, 50, 52-55, and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pars et al. (U.S. Patent No. 3,728,360) in view of McNally et al. (U.S. Patent No. 5,653,961).

Response to Arguments

In the remarks filed April 19, 2007, Applicants did not address the merits of the instant rejection. This rejection is maintained for the reasons of record and because Applicants' silence regarding the merits of this rejection is interpreted as an implicit acknowledgement of the propriety of the instant rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 43, 46, 48, 50, and 52-55 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,509,005 (USPN '005) **is maintained** for the reasons of record set forth in the office action mailed on December 28, 2005. New claims 57-60 are appended to this rejection for the reasons of record. New claims 57-60 are appended to this rejection for the reasons of record. In summary, **claims 43, 46, 48, 50, 52-55, and 57-60 are on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,509,005 (USPN '005).**

Response to Arguments

In Applicant's remarks filed April 19, 2007, Applicants did not address the merits of the rejection of claims 43, 46, 48, 50, and 52-55 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,509,005 (USPN '005). Previously, Applicants have stated that a terminal disclaimer would be forthcoming (see

remarks submitted on September 13, 2006). To date no terminal disclaimer has been filed, thus the instant rejection is maintained.

Claims 43, 46-48, 50, 52-55, and 57-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 13-14, and 16 of U.S. Patent No. 6,713,048 (USPN '048). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of USPN '048 anticipate the claims of the instant invention, because everything that is instantly claimed is fully encompassed by the claims of USPN '048. Independent claim 57 of the instant application claims an aerosol-dispensable pharmaceutical composition comprising: tetrahydrocannabinol and hydrofluoroalkane, wherein the composition is aerosol-dispensable. Independent claim 1 of USPN '048 claims a method of administering a pharmaceutically effective dose of aerosolized delta-9-tetrahydrocannabinol to a patient comprising (i) providing a solution comprising a pharmaceutically acceptable form of delta-9-tetrahydrocannabinol (THC) in a hydrofluoroalkane, said solution having not more than 15% w/w of a pharmaceutically acceptable solvent; (ii) aerosolizing the THC solution to provide respirable droplets comprising THC wherein at least 20% of the mass of the respirable droplets comprises droplets having an aerodynamic diameter of less than 5.8 microns; and (iii) administering a pharmaceutically effective dose of said respirable droplets to a patient's lungs. The remaining cited claims of USPN '048 have the same or substantially similar limitations, which obviate the limitations of the rejected dependent claims of the instant invention. The composition used in the claimed method of USPN '048 is essentially the same composition currently claimed by Applicants.

Thus, a person of ordinary skill in the art at the time of the instant invention would conclude that claims 43, 46-48, 50, 52-55, and 57-60 of the instant invention are *prima facie* obvious over claims 1-5, 13-14, and 16 of U.S. Patent No. 6,713,048 (USPN '048).

Conclusion

Claims 43, 46-48, 50, 52-55, and 57-60 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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